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April 23, 2002

Lester M. Crawford, Jr., D.V.M., Ph.D.
Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford,

The Society for Research on Nicotine and Tobacco (SRNT) petitions the Food and Drug Administration (FDA) to regulate SF Garrett's Nicotine Water. We are also submitting similar petitions on Omni and Advance cigarettes and Ariva. In addition, we have attached two similar petitions we sent to the agency on Eclipse. We are disappointed that no apparent action has been taken regarding Eclipse.

SRNT (www.srnt.org) is composed of over 600 of the leading scientists researching nicotine and tobacco issues in the US and 33 other countries. Many of our members have served on WHO, FDA and other governmental/public organizational committees. One of SRNT's major missions is to provide scientific information and advice to policy makers.

Our reasons for urging the FDA to regulate Nicotine Water are similar to those outlined in our Eclipse petition and include the following:

- Traditional cigarettes are known toxic nicotine delivery products that are widely available and cause a huge amount of harm. Thus, we would reiterate the continuing and urgent need for FDA to regulate traditional cigarettes
- The current scientific database suggests it is feasible to develop nicotine delivery products that are less toxic than current cigarettes. As the Institute of Medicine concluded, under the appropriate conditions, such products could reduce the risk of tobacco use¹.
- Nicotine Water (www.nicotinewater.com) advertising either explicitly or implicitly states it is less harmful than smoked tobacco; e.g. it states "nicotine water was conceived as a healthier alternative to cigarettes." Although this may be true,² we are unaware of a scientific analysis of the magnitude of this risk reduction, how much risk remains in nicotine water and how this risk compares to both cigarettes and nicotine replacement therapy. The recent Institute of Medicine report stated such information is necessary to allow promotion of a product as a substitute for cigarettes

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and outlined the types of research that would need to be done to allow such promotion¹.

- Also explicit in Nicotine Water advertising is that the product would mitigate withdrawal symptoms and craving and could be used by smokers who "cannot smoke at their places of work" or "who wish to quit smoking." Unlike existing medications, we know of no published data on the efficacy of Nicotine Water on these either of these outcomes.
- A scientific analysis of the reduction in risk from Nicotine Water is important because smokers do believe and often overestimate health claims. For example, a recent NCI Monograph³ concluded that most smokers believe low tar/nicotine cigarettes are safer even though these products make only vague implicit health claims in their advertising. The NCI report also concluded the health benefits of low tar/nicotine cigarettes are either non-existent or very small.³ Finally, recent scientific^{4,5} and industry documents⁶ suggest the marketing of low tar/low nicotine cigarettes has undermined many smokers intentions to stop smoking. We fear the same may be true for Nicotine Water.



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- New products can produce unexpected new risks. For example, light cigarettes increase adenocarcinoma of the lung³ and Eclipse increases carbon monoxide (CO) levels⁷ and produces inhalation of fiber glass particles;⁸ a comprehensive analysis of any risks by Nicotine Water is needed.
- It is unclear how Nicotine Water will be used. If smokers use Nicotine Water as advertised; i.e., to avoid smoking restrictions, they may simply add nicotine exposure to their ongoing daily consumption of cigarettes. If this were true, nicotine could actually increase risk for smokers.
- The availability of Nicotine Water along with implicit or explicit claims of it being safer than cigarettes might increase initiation of smoking or undermine motivation for stopping smoking.¹ The Institute of Medicine report also raised this concern.

In summary, SRNT believes there are many unanswered questions about the impact of Nicotine Water on public health. Thus, SRNT urges the FDA to institute regulatory procedures to require sufficient study of Nicotine Water so that the policy mistakes that were made with low-tar/low-nicotine cigarettes^{1,3} are not repeated.

Sincerely,

John R. Hughes, M.D.
Chair, Policy Committee
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May 3, 2002

Ms Jennie Butler
Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: SRNT petitions on Omni/Advance, Arriva and Nicotine Water

Dear Ms Butler,

I certify that, to the best of my knowledge, the above three petitions includes the pertinent information relevant to the petition, favorable or not. Since we are not requesting approval of a food or product or that a food be categorized as GRAS, we do not believe an environmental impact statement is needed.

Attached are the Eclipse letters left out of the above petitions.

Sincerely,

John R. Hughes, M.D.
SRNT Policy Committee

Encl.



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March 19, 2001

Bernard A. Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Schwetz,

The Society for Research on Nicotine and Tobacco would again suggest to the FDA the need for and urgency to regulate Eclipse and other products that claim or infer to reduce exposure to tobacco toxins. Enclosed is a copy of our prior letter to former FDA Commissioner Henney on this matter.

We are reiterating this request for two reasons. First, the recent findings of the National Academy of Science's Institute of Medicine report, "Clearing the Smoke." This report summarized research around Eclipse and Eclipse-like products and concluded that such products "have not yet been evaluated comprehensively enough . . . to provide a scientific basis for concluding they are associated with a reduced risk of disease" and "the net impact on the health of the population as a whole [of Eclipse-like products] could, in fact, be negative."

Second, recent scientific findings suggest Eclipse might present a new harm via exposure to glass fibers from Eclipse. Yet RJR has not warned consumers of this.

Third, since we last wrote even more reduced risk products have been either marketed or are in development. First, RJR has expanded their market to direct-to-consumer sales in 1700 retail outlets in the Dallas-Ft Worth area. Star Scientific has marketed a new cigarette it claims has reduced carcinogens "Vantage", Philip Morris has introduced a "reduced smoke" product (Accord) and Brown and Williamson and Vector Group are developing reduced risk cigarettes. All this activity in the last few months clearly indicates, that this issue will not go away and that FDA urgently needs to take a stand about regulation of these products before its credibility is seriously questioned.

Sincerely

John R. Hughes, M.D.
Chair, Policy Committee, SRNT

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Executive Director

June 16, 2000

Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Regulation of Eclipse

Dear Dr. Henney,

The Society for Research on Nicotine and Tobacco (SRNT) urges The Food and Drug Administration to review the health claims RJ Reynolds is making for their Eclipse product. We believe there is insufficient and contrary scientific results to support these claims and thus FDA should institute some form of regulatory procedures over Eclipse.

Our society consists of 600+ of the leading scientists in tobacco and nicotine research in the US and 33 other countries; thus, SRNT is the largest repository of scientific information in the world. One of SRNT's major missions is to provide scientific data and advise to policy makers.

Our reasons for urging FDA to review Eclipse health claims are as follows:

- Smokers do believe and often overestimate health claims made by the tobacco industry. For example, a recent NCI/ Presidential Commission report ¹ (and other studies ²) concluded that most smokers believe low tar/nicotine cigarettes are safer even though these products make only vague implicit health claims in their advertising. The NCI report (and other reports ³) also conclude the health benefits of low tar/nicotine cigarettes are either non-existent or very small. Finally, recent scientific ^{2,4} and industry documents ⁵ suggest the marketing of low tar/low nicotine cigarettes has undermined many smokers intentions to stop smoking.
- Although there are data that Eclipse delivers fewer carcinogens than regular cigarettes, ⁶⁻¹⁰ there are problems with these data. For example, machine-testing data ⁶⁻⁸ must be interpreted cautiously because experience with low tar/nicotine cigarettes clearly shows that people do not smoke like machines do. ³ To our knowledge, there are only two published studies of carcinogen exposure in

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humans using Eclipse.^{9:10} These studies used small samples, short durations of exposure and were conducted by the tobacco industry.

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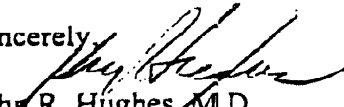
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Sarah L. Evans
Executive Director

- Both an independent study¹¹ and an industry study¹² found that use of Eclipse increased carbon monoxide (CO) levels compared to smoking traditional cigarettes. This is important as increased CO is linked to cardiovascular disease¹³ and smokers are more likely to die of tobacco-induced cardiovascular diseases than of tobacco-induced cancers¹⁴.
- Eclipse exposes smokers to inhalation of fiber glass particles;¹⁵ thus, Eclipse may add a new risk of cancer and lung diseases.
- It is unclear how Eclipse will be used. The only study of the use pattern of Eclipse did not present Eclipse in the manner that RJR is pursuing.¹¹ Smokers might substitute Eclipse for cigarettes. On the other hand, they might use Eclipse solely to avoid smoking restrictions and just add Eclipse use to their ongoing daily consumption of cigarettes. If the later is true, Eclipse could actually increase risk.
- The availability of Eclipse along with claims of it being a safer cigarette might increase initiation of smoking or would undermine motivation for stopping smoking. Although an initial study suggests that Eclipse does not undermine motivation to quit,¹¹ this study lacked an adequate control group to clearly answer the question.

In summary, SRNT believes there are many unanswered questions about the validity of the health claims made by Eclipse.^{16:17} In fact, we believe the availability of Eclipse could result in a net worsening of public health due to increased CO levels, glass inhalation, higher rates of initiation of smoking, or lower rates of cessation of smoking. In addition, other cigarette substitutes (e.g. Accord) and "safer tobacco" products (e.g. Star Tobacco) are likely to make health claims in the not too distant future. Thus, SRNT urges the FDA to institute regulatory procedures to require sufficient study of Eclipse so that the policy mistakes that were made with low-tar/low-nicotine cigarettes are not repeated with Eclipse and other smoking products making health claims.

Sincerely,


John R. Hughes, M.D.
Chair, Policy Committee
SRNT

cc: Geoff Mumford
Judy Wilkenfeld
SRNT Office
Bill Corrigan

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